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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/383,054 08/25/99 EDWARDS

D AIR-108PA

HM12/1121
CAROLYN S. ELMORE
HAMILTON BROOK SMITH & REYNOLDS P C
TWO MILITIA DRIVE
LEXINGTON MA 02421-4799

EXAMINER

PULLIAM, A

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

11/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/383,054

Applicant(s)

EDWARDS ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-127 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-127 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

The Amendment A, filed October 2, 2000, has been entered. Accordingly, claims 1-49 have been canceled and claims 50-127 are pending. Receipt is acknowledged of the Request for Extension of Time and the Supplemental Information Disclosure Statement, both received October 2, 2000.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50-127 rejected under 35 U.S.C. 103(a) as being unpatentable over Durrani *et al* (hereinafter Durrani). Durrani discloses a process to directly spray dry a drug/lipid powder composition comprising preparing an aqueous solution containing a drug and a lipid containing ethanol solution. The mixture is then spray dried to get particles (p 40, claim 1). Durrani further teach that the drug may be selected from a group which includes insulin, granulocyte colony stimulating factor, interferons, growth factors, calcitonin, and interleukins (p 40, claim 2), as well as peptide hormones, and lung surfactant proteins (p 10-11). Durrani further teaches that the lipid may be selected from the group consisting of phosphatidylglycerol, phosphatidylcholine, phosphatidylinositol, phosphatidylethanolamines, and phosphatidylserine (p 41, claim

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4). Lastly, Durrani teach that the diameter of the resulting particles is between 0.1 and 20 microns (p 14, l 30).

Durrani does not disclose the percent protein integrity of the tap density of the spray dried particles. However, based on the fact that Durrani discloses the same components for the spray dried particles, it is the position of the examiner that the protein integrity and tap density are inherent characteristics, and would be the same as those claimed by applicant, absent the presentation of some unusual and/ or unexpected results. Further, on page 8 of the specification, applicant states that spray dries particles which have decreased stability are those without a phospholipid or with just an aqueous solvent. Durrani teaches the inclusion of phospholipids and organic solvents in his particles, so therefore, his particles would have the same improved characteristics as claimed by applicant.

In addition, Durrani does not teach that the phospholipid be present at 10 weight percent. However, Durrani does not specify a specific amount of the ingredients. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

One of ordinary skill in the art would have been motivated to make a spray dried composition of a drug and a lipid based on the generic claim of Durrani. The expected result would be a stable spray dried powder formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant has amended the generic claim to include a specific weight percent of the phospholipid. Therefore, the rejection under 35 U.S.C. 102(b) is no longer applicable.

Applicant's arguments regarding the rejection under 35 U.S.C. 103(a) have been fully considered but are not found persuasive. Applicant argues that Durrani does not teach a method to create particles which consist essentially of a protein and a phospholipid. However, according to the MPEP section 2111.03, the transitional phrase "consisting essentially of" limits the scope of the claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). The novel characteristic of the instant application is a stable spray dried protein formulation. It is the position of the examiner that Durrani has achieved this same goal of a stable spray dried formulation, and therefore any additional ingredients included in Durrani's formulation have not materially affected the basic and novel characteristic of the formulation. Further, Durrani's disclosure is not limited to the scope of his examples. Claim 1 states simply a process for spray drying a drug/lipid powder

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composition comprising, mixing an aqueous solution of drug and a lipid containing ethanol solution, and spray drying to form particles. There is no mention in this broad claim of any other ingredients. Therefore, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

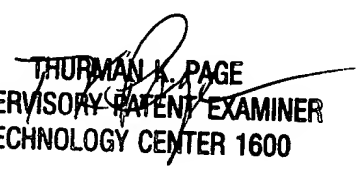
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7922 for regular communications and (703) 308-7922 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E, Pulliam
Patent Examiner
Art Unit 1615
November 16, 2000


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600